SUBJECT:	Fermilab Corrective & Preventive Action Procedure	**NUMBER:**	**1004.1001**
RESPONSIBILITY:	Quality Assurance Manager	**REVISION:**	002
APPROVED BY:	Head, Office of Quality and Best Practices	**EFFECTIVE:**	**05/01/2012**

1.0 Purpose

The purpose of this procedure is to implement a corrective and preventive action (CAPA) program for continuous improvement in compliance with DOE O 414.1C Contractor Requirements Document Section 3c Management/Criterion 3 – Quality Improvement.

2.0 Scope

This procedure is followed when corrective and preventive actions are necessary to correct quality program nonconformities or opportunities for improvement. This procedure applies to all Fermilab employees, subcontractors, and users performing formal corrective or preventive actions in the quality program.

3.0 Responsibilities

3.1 The Fermilab Director

- Holds senior staff accountable for implementation of, and compliance with, this procedure

3.2 Division/Section/Center Heads

- Comply with and support this procedure for their areas of responsibility
- Ensure timely response, submittal, and implementation of Corrective & Preventive Action Plans (CAPs) that are appropriate to the level of risk associated with a nonconformity or opportunity for improvement
- Provide the necessary resources to develop and implement CAPs
- Analyze individual and collective nonconformities or opportunities for improvement to detect trends or potential systemic weaknesses

3.3 The Office of Quality and Best Practices (OQBP)

- Manages, improves and administers the Fermilab Corrective and Preventive Action Program
- Requests, reviews and tracks CAPs for nonconformities or opportunities for improvement relevant to the issues tracked by the Fermilab Assurance Council
- Requests, reviews and tracks CAPs for nonconformities or opportunities for improvement identified during assessments or audits sponsored or conducted by OQBP
- Advises the Chief Operating Officer if a nonconformity appears to be reportable to the DOE Occurrence Reporting and Processing System (ORPS)
- May analyze individual and collective nonconformities or opportunities for improvement to detect trends or potential systemic weaknesses

3.4 All Employees, Contractors, and Users

- Identify and report nonconformities and opportunities for improvement to line management
- Participate in corrective and preventive actions as requested by line management
- Complete corrective and preventive actions commensurate with the level of risk as assigned

4.0 Procedure

4.1 Corrective & Preventive Action Procedure

This procedure is intended to provide terminology and basic structure for problem investigations. It is applied to non-ES&H corrective and preventive actions and to ES&H corrective and preventive actions of reported incidents, events, or accidents as defined in FESHM 3020, Incident Investigation and Analysis, findings assigned risk assessment code of 1 or 2, or repetitive events in conjunction with FESHM 1040.3, Risk Assignment.

Figure 1 is an illustration of the generalized process for feedback and continuous improvement utilized in the Fermilab corrective and preventive action program.

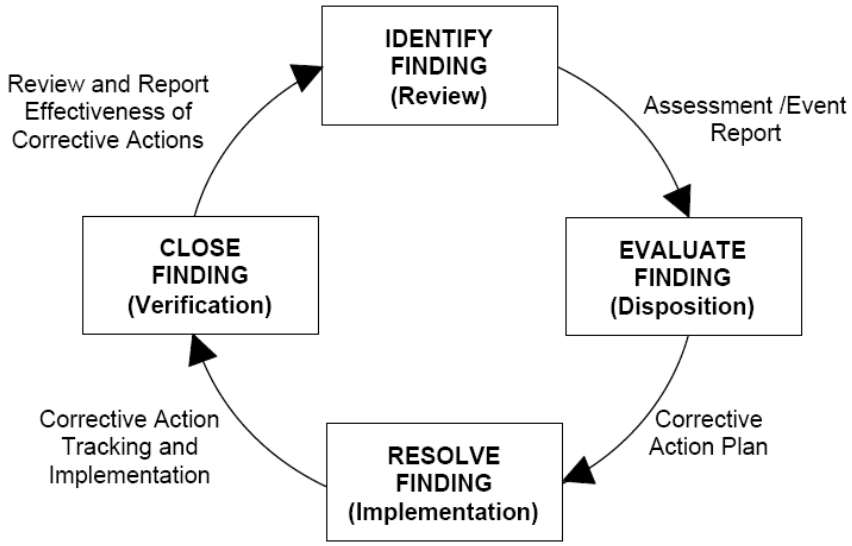

Figure 1. Feedback and Improvement

4.1.1 The sequence begins with the identification and reporting of a nonconformity or opportunity for improvement.

All employees, contractors, subcontractors, and Fermilab users are encouraged to report any nonconformities or opportunities for improvement to their immediate supervisor. Other sources of nonconformities may be identified during routine item inspections and tests, reviews, assessments or audits. Persons leading such reviews, assessments or audits may request CAPs from affected line management in order to close open findings. In some cases OQBP may request CAPs from line management on behalf of persons who lead a Fermilab review, assessment or audit. OQBP may also request CAPs as a result of an assessment conducted by or sponsored by OQBP or for items entered into the Issues Management System.

4.1.2 Responsible line management will respond to the CAP request. Depending on the complexity of the nonconformity or opportunity for improvement, the response may

contain a planned date for a completed corrective action plan (CAP), or it may contain a completed CAP. If the CAP is not submitted with the response, the responsible manager submits the CAP to the requestor at a later date as indicated in the response. The Fermilab Corrective Action Plan Form 1 1004.1001 Form 1 is used to submit a CAP.

Each CAP will contain detailed information regarding department/division/section/center responsible, who is designated to manage resolution, facts supporting the identification of root cause, lessons learned (where relevant), and timelines for resolution commensurate with the complexity, and actual or potential significance/risk.

A graded approach is used to perform root cause analysis. This approach matches the risk level and severity of the nonconformity with the level of resources and depth of examination used to perform the root cause analysis. See the Fermilab Root Cause Analysis Procedure 1004.1002 for guidance on conducting a root cause analysis.

During a root cause analysis the responsible person may question not only if existing controls need to be updated but also whether or not the activity has the correct controls under current operating conditions. Under these circumstances the Fermilab Graded Approach Procedure, 1002.1000 may be applied where the responsible person determines that corrective or preventive actions require a more formal approach to risk evaluation and control selection.

The CAP should also contain a description of opportunities for preventive actions that will be undertaken to prevent the occurrence of this or similar events in the same and / or different areas when such opportunities are identified. If corrective actions will require significant time to complete and implement, the CAP must include interim corrective and/or remedial (compensatory) measures that will be implemented pending completion of the corrective action to reduce the possibility of the event or condition recurrence. Where corrective actions require training or re-training, records of such training are maintained.

4.1.3 The requestor of the CAP reviews the response and CAP for:

- Completeness, and correct identification of the cause
- likelihood of resolving the identified root cause of the issue,
- likelihood of preventing recurrence in the area where identified,
- identification of lessons learned if applicable,
- likelihood of preventing the occurrence of similar issues in the same area or other areas of the laboratory.

4.1.4 Upon acceptance of the CAP, the responsible person implements the necessary actions.

4.1.5 The responsible person notifies the requestor upon completion of the necessary actions.

4.1.6 The requestor ensures completion is verified before closing the corrective action request.

4.1.7 After a corrective action request is closed, it may be subject to validation by the requestor, and/or responsible person, to determine the effectiveness of actions taken. Corrective actions are effective when the causal chain of events leading up to the problem or opportunity are broken and remain broken. Degree of validation will be commensurate with complexity, risk and cycle time associated with affected processes. Some corrective /

preventive actions may be validated formally by inspections, tests, reviews, surveillances, audits or other assessments. Other issues may simply be monitored to ensure the ongoing effectiveness of the actions taken.

4.2 **Management Review of Corrective & Preventive Action Data**

Responsible line management will analyze individual and collective problems or opportunities for improvement to detect trends or potential systemic weaknesses, and to identify additional opportunities for preventive actions.

5.0 Records

Corrective & Preventive Action Plans
Reports of QA Reviews, Assessments, Audits, Inspections, Tests, etc

6.0 Review Cycle

6.1 Document Owner
OQBP QA Manager

6.2 Reviewers
OQBP Head
D/S/C QARs
OQBP Staff
SSO representatives
ES&H Section Head

6.3 Approver
OQBP Head

7.0 Policy and Program Documents

Directors Policy #10, Quality Assurance
1001 Integrated Quality Assurance (IQA)
1002.1000 Fermilab Graded Approach Procedure
1004.1001 Form 1 Fermilab Corrective & Preventive Action Plan Form 1
1004.1001 Guide 1 Fermilab Corrective & Preventive Action Plan Guide 1 to Form 1
1004.1002 Fermilab Root Cause Procedure
Fermilab ES&H Manual (FESHM) Chapter 1040.1, ES&H Self Assessment Program
Fermilab ES&H Manual (FESHM) Chapter 1040.3, Risk Assignment
Fermilab ES&H Manual (FESHM) Chapter 3010, Significant and Reportable Occurrences
Fermilab ES&H Manual (FESHM) Chapter 3020, Incident Investigation and Analysis

8.0 Definitions

Assessment: A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Corrective Action: Action to eliminate the cause of a detected nonconformity or other undesirable situation.
Note: There can be more than one cause for a nonconformity. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Nonconformity: Non-fulfillment of a requirement.
Note: A nonconformity can be any deviation from work standards, practices, procedures, legal requirements, or applicable code of federal regulations.

Preventive Action: Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
Note: There can be more than one cause for a potential nonconformity. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

Remedial Action: an action taken to alleviate the symptoms of existing nonconformities or any other undesirable situation. Also known as correction or compensatory action, remedial action is used to minimize the effects before the root cause and best solution may be identified. It is a reactive, short term action to stop immediate effects of the problem.

Root Cause: An identified reason for the presence of a defect or problem. The most basic reason, which if eliminated, would prevent recurrence. The source or origin of an event. Root cause is also known as the system cause.

9.0 References

DOE O 414.1C Quality Assurance – Contractor Requirements Document, Attachment 2 Management/Criterion 3 – Quality Improvement
DOE G 414.1-5 Corrective Action Program Guide

Appendix 1 – CAP Form Instructions

These instructions explain how and when to fill in the various fields and sections of the CAP form. The CAP form is used to initiate and track corrective actions for nonconformities and opportunities for improvement. The CAP form contains four main sections that are completed by specified individuals in chronological order. All fields are required unless explicitly labeled optional.

The first section to be completed is the CAP initiation section. It is filled in by the person requesting the corrective/preventive actions. For CAPs generated by an OQBP led QA assessment this person is the lead assessor. The following fields are completed:

CAP Initiation section

Requestor name: Name of person requesting the corrective/preventive actions

Organization: Division/Section/Center **(**D/S/C) of the requestor – for OQBP led assessments this is OQ

Phone: Four digit phone extension of the requestor

Nonconformity/Opportunity to be addressed: description of the nonconformity or opportunity for improvement. This should always reference the specific requirements not met (IQA, Engineering Manual etc.) chapter and verse for nonconformities

Unique Tracking Number: CAP identification number of the format DS-YYYYMMDD-xx where DS=Division, Section or Center, YYYYMMDD= Date Opened, and xx=sequence number (01, 02, 03… etc.)

Other Tracking Number: Additional tracking number such as ESHTRAK#, DMR#, etc. For CAPs generated by an OQBP led QA assessment this field contains the assessment ID. This field is optional

Responsible Person: Name of person responsible for ensuring that the preventive/corrective actions are implemented. This may or may not be the same person as the person named under "Who will complete the work" below.

Division/Section/Center: D/S/C of the responsible person

Department/Group: Department or group of the responsible person.

Phone: Four digit phone extension of the responsible person

Comments: Information the requestor feels is important for understanding the Corrective action request. This field is optional

Once all of the entries in the CAP Initiation section have been completed the form is sent to the person identified in the ***Responsible Person*** field and to the OQBP QAE who maintains the OQBP tracking system when the CAP is

issued by OQBP staff. The responsible person then completes the second section of the form – CAP development. This section contains the following fields:

CAP Development section

CAP version: Current CAP version number. Start with '01' and increment by one each time the CAP is updated or modified

Describe the Actual Nonconformity/Opportunity, and What Caused it (Root Cause): Brief restatement of the nonconformity and description of its root cause

Remedial/Compensatory, Corrective, and/or Preventive, actions being taken and (where applicable) Lessons Learned: Description of the corrective (including any remedial or compensatory) and preventive actions that will be taken to eliminate the identified root cause. Also a description of lessons learned if appropriate.

Planned start date: Date (using the format YYYYMMDD) that implementation of corrective/preventive actions will begin

Key milestones and Dates: Key milestones during the implementation of corrective/preventive actions and the dates they will be completed using the format YYYYMMDD. These are typically used for actions that require more than a few weeks to complete.

Estimated date for completion: Date (using the format YYYYMMDD) that implementation of corrective/preventive actions will be complete.

Who will complete the work: Name of person who will implement the corrective and preventive actions.

Phone: Four digit phone extension of person who will implement the corrective and preventive actions

Who will perform verification: Name of person who will verify the effectiveness of the corrective and preventive actions in eliminating the root cause. For OQBP led assessments this will be the requesting QAE.

Phone: Four digit phone extension of person who will verify the effectiveness of the corrective and preventive actions.

Comments: Information the responsible person feels is important for understanding the corrective and preventive actions to be implemented. This field is optional

Once all of the entries in the CAP Development section have been completed the form is sent to the manager of the person identified in the ***Responsible Person*** field and to the OQBP QAE who maintains the OQBP tracking system when the CAP is issued by OQBP staff. The ***Approval Manager*** then completes the third section of the form – CAP Approval. This section contains the following fields:

CAP Approval section

Approval Manager: signature of the manager of the responsible person, signifying they agree that the work described in the CAP Development section will be performed by the responsible person in the specified time frame.

Date: Date (using the format YYYYMMDD) that approval manager signed the CAP

Comments: Information the approval manager feels is important for understanding the implementation of the corrective and preventive actions. This field is optional

Once all of the entries in the CAP Approval section have been completed the form is sent to the persons identified in the ***Who will complete the work*** field, the ***who will perform verification*** field, and the ***Requestor name*** field. These persons then complete the fourth and final section of the form – CAP Closure – in the order specified below. This form is also sent to the OQBP QAE who maintains the OQBP tracking system when the CAP is issued by OQBP staff. This section contains the following fields:

CAP Closure section:

Description of actions taken to implement (if different than plan): Description of corrective and preventive actions taken if they were different than the ones described in the CAP development section

1. **Work completed By:** Signature of the person who completed the corrective and preventive actions, signifying all actions are complete.

   Date: Date (using the format YYYYMMDD) the implementer signed the CAP

2. **Verified By:** Signature of the person who verified the corrective and preventive actions signifying the actions were effective in eliminating the root cause.

   Date: Date (using the format YYYYMMDD) the verifier signed the CAP

   Comments: Information the verifier feels is important for understanding the closure of this CAP. This field is optional

3. **Acceptance Requestor:** Signature of the person who the initiated the CAP, signifying the corrective and preventive actions were effective in eliminating the root cause.

   Date: Date (using the format YYYYMMDD) the requestor signed the CAP

Comments: Information the approval manager feels is important for understanding the closure of this CAP. This field is optional

Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft- Separated from OQBP IMS Issues Tracking Procedure Added reference to a Guide in addition to a Form.	000	08/06/08
Jed Heyes	Changed formal root cause to complex root cause and informal investigation to simple root cause. Added definitions for the terms.	000 A1	08/08/08
Jed Heyes	Clarified complex and simple corrective / preventive actions. Introduced a new Form 1 for simple actions (used in low risk situations) and reassigned original Form 1 to Form 2 for complex actions.	000 A2	10/26/08
Jed Heyes	Updated from document review with Bob Grant, & Nathan Weed	000 A3	12/23/08
Jed Heyes	All changes accepted upon OQBP approval on 01/13/09. Promotion to C life cycle for simultaneous review (B life cycle) and use (C-validation life cycle) by QARs & QAEs during As-Is assessments..	000 C	02/02/09
John Martzel, Jed Heyes	Updated the document to resolve CAP OQ-20100104-01 generated by 2009 DOE Assessment of Fermilab Quality Assurance Program. Key changes: • Removed references to simple and complex corrective actions and root causes and replaced with references to a graded approach • Defined the term nonconformity • Removed 1004.1001 guide 2, Complex Corrective and Preventive Action Plan, from the process • Removed Appendix describing required root cause depth (simple/complex)	001	03/25/10
Jed Heyes	Updates by the ES&H / OQBP CAPA taskforce (J Heyes, J Cassidy, M Bonkalski, A Pavnica) to harmonize with applicable FESHM chapters. Also addresses CD and TD	001 A	12/01/2010

	comments. Clarified scope, added FESHM cross references and definitions, other editorial changes but changes to the procedure steps in section 4.		
Jed Heyes	Promoted for publication	001.1	03/09/2011
Jed Heyes, John Martzel	Added Appendix one which contains instructions for filling out the CAP form	002	5/1//2012